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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,362	07/07/2003	Christopher J. M. Meade	1/1363	7889

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/614,362	MEADE ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *9-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 35-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The finality of the last Office Action is withdrawn.

Applicants' Reply filed May 30, 2006 is acknowledged. Claims 1-37 are pending. Claims 1-8 and 35-37, drawn to pharmaceutical compositions, kits and therapeutic methods, remain under consideration. Claims 9-34, drawn to non-elected subject matter, remain withdrawn from consideration, 37 CFR 1.142(b).

A Terminal Disclaimer filed May 30, 2006 is further acknowledged and has been accepted. Accordingly, the rejection of record under the judicially created doctrine of obviousness-type double patenting is withdrawn.

A Notice of Appeal filed June 1, 2006 is further acknowledged.

In the last Office Action claim 35 was rejected in the last Office Action under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and practice the invention with respect to prevention of any inflammatory or obstructive disease of the respiratory tract.

Subsequent to the deletion of the term "prevention" and the limitation of claim 35 to diseases selected from the group consisting of asthma, chronic obstructive pulmonary disease, pulmonary hypertension, allergic and non-allergic rhinitis, the rejection of record is withdrawn. However, the same rejection was inadvertently not applied to claim 37, a claim that is also drawn to the "treatment and/or prevention of an inflammatory or obstructive disease". Accordingly, claim 37 is presently rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that is not described in the specification in such a way as to enable one skilled in the art to which it pertains to

make and practice the invention with respect to prevention of any inflammatory or obstructive disease of the respiratory tract. The same reasons for the rejection of claim 35 under 35 U.S.C. 112, first paragraph, apply to claim 37.

Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Parenthetical subject matter renders the claim in which it appears indefinite. It is unclear whether or not a claim limitation is intended. Applicants have employed three distinct types of nomenclature to depict those NK_1 receptor antagonists contemplated. For uniformity, each compound should be recited by the name that is most readily recognized, as, for example, N-[2-(3,5-bis-trifluoromethylphenyl)ethyl]-2-{4-[(3-hydroxypropyl)methylamino]piperidin-1-yl}-N-methyl-2-phenylacetamide.

Clarification is required.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 and 36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-18 of Eickmeier et al., U.S. Patent No. 6,696,462 in view of Pieper, M.P., US 2006/0183726.

Eickmeier teaches a combination composition comprising a compound of formula 1 wherein when A and B = -CH=CH- and R, R^1 and R^2 are methyl, the anticholinergic differs from that presently claimed by a cyclopropyl group in place of an epoxy group. The anticholinergic compound is combined with an antiallergic which may be an NK_1 receptor antagonist. For example, saredutant is an antiallergic agent. Pieper teaches equivalence among anticholingerics in the treatment of respiratory diseases. See page 4, paragraph [0106].

Claims 1-8 and 35-37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of Pairet et al., U.S. Patent No. 6,696,042 in view of Pieper, M.P., US 2006/0183726.

Pairet teaches a pharmaceutical composition comprising the anticholinergic tiotropium and the same NK_1-receptor antagonists that are presently claimed for use in the treatment of respiratory diseases. Pieper teaches equivalence among anticholingerics in the treatment of respiratory diseases. See page 4, paragraph [0106].

Claims 1-8 and 36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of Meissner et al., U.S. Patent No.

6,706,726. Although the conflicting claims are not identical, they are not patentably distinct from each other because when A forms an epoxy group and R^1, R^2 and R^7 are methyl, the anticholinergic is the compound of instant formula 1 that is combined with an antiallergic agent to treat asthma or COPD. Saredutant, an example of an NK_1 receptor antagonist, is an antiallergic agent.

Pieper, M.P., EP 1 632 229, is cited to show further the state of the art with respect to equivalence among long-acting anticholinergics in a medicament. Van Cauwenberge, P., Allergy: European Journal of Allergy and Clinical Immunology (abstract), and Maghni et al., American Journal of Respiratory and Critical Care Medicine (abstract), are cited to show further the state of the art with respect to the use of saredutant, an NK_1 receptor antagonist, as an antiallergic agent.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

September 11, 2006 Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER